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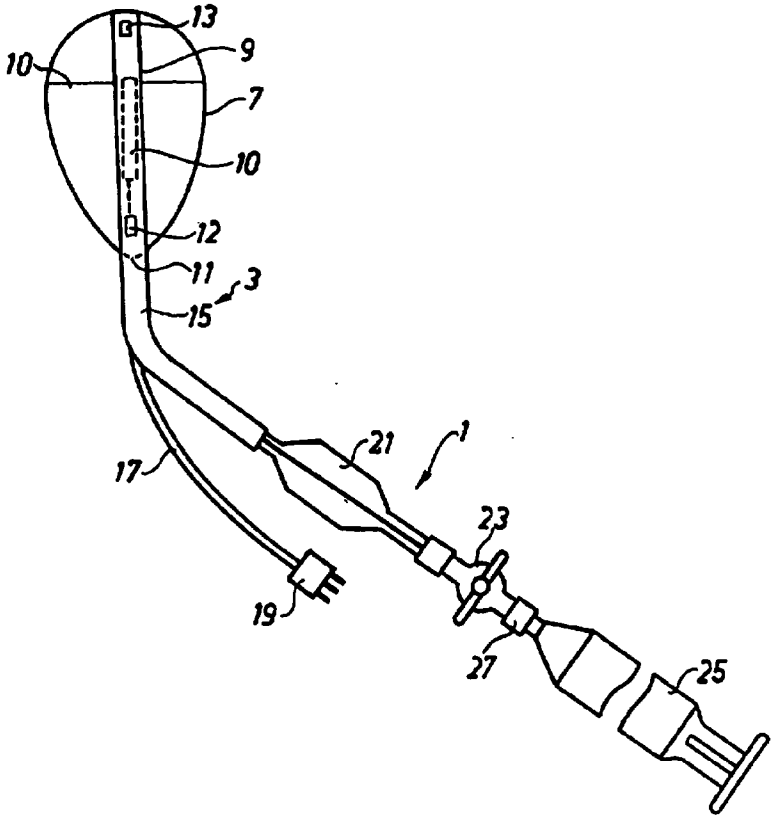
(57) Abstract

Device for carrying out heat treatment, so-called hyperthermia, in a body cavity or a duct, comprising a catheter intended to be filled with heat-transferring medium and provided with an elongate front part (3) intended to be introduced into said cavity or duct and comprising a centrally positioned heat-releasing element (10), which is either surrounded by an elongate housing (9) or per se constitutes such housing, and a flexible and/or elastic balloon (7) surrounding said housing (9) in a liquid-tight manner, and first means (25) for expanding the balloon by the supply of heat-transferring medium, and second means (21; 93) for internal circulation of said medium through the housing (9). The device is characterized in that said second means (21; 93) is placed in series with said first means (25) and said first housing inlet (11) and comprises a first chamber (29) of variable volume which via inlet (35) and outlet (37) forms a connection between said first means (25) and said first housing inlet, said first chamber and possibly other chambers with inlets and outlets in the catheter being arranged in such a manner that the highest point of each chamber is positioned at the same level or lower than the highest point of the transition of the chamber (29) into the outlet (37).



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Device for carrying out hyperthermia in a body cavity

The present invention relates to a device for carrying out heat treatment, so called hyperthermia, in a body cavity or body duct. The device in question can be said to be constituted by a so called balloon catheter for carrying out heat treatment of areas in a living body including man.

Background of invention

In balloon catheters of this type heating of the liquid which after insertion of the catheter balloon into the organ to be treated is used for expanding the balloon. The heating takes place by means of an element positioned in the balloon for release of heat to the liquid and further on to the interior walls of the cavity, the liquid in certain designs being brought to circulate in the expanded balloon by means of some type of pump system. A number of different types of balloon catheters for the heat treatment of body cavities are known, and in certain cases it has been suggested that the heated liquid be circulated inside the balloon for reaching an even heat distribution in the expanded balloon and an efficient heat transfer to the surrounding tissues.

In US patent 4,949,718 there is described a balloon catheter for the destruction of uterus mucosae by means of heating, the heating taking place via a liquid which by means of an electric heating element comprising a spiral surrounded by a screen provided with holes is heated to a temperature at or near the boiling point of the liquid. In this system there will be obtained a certain self-circulation in view of the fact that the liquid is heated to a temperature near its boiling point. The disadvantage of this device is, however, that a sudden steam formation in an uncontrollable manner can increase the pressure in the cavity with concomitant risk for rupture

in the uterus muscle. Furthermore, no efficient heat transfer to the surrounding tissues will be obtained in view of the lack of forced circulation of the liquid.

In US patent 4,160,455 there is described a device for heat treatment of a body cavity, where a heat medium in the form of a liquid is heated by electric resistance elements and brought to circulate within an enclosure in order to distribute the heat and improve the heat transfer to the surrounding. The circulation is provided by means of a bellow system generating an oscillating movement, and by a system of back valves in a housing surrounding the heating element the oscillating movement of the liquid is transferred to a circulating movement.

In PCT-application SE94/00208 there is described a balloon catheter for hyperthermal treatment of body cavities, for example uterus, where a balloon after insertion into the cavity is brought to expand by means of a liquid heat medium injected into the rear or proximal end by means of for example a piston syringe. The heating device consists of a self-regulating material having a so called Curie-point, and the energy supply is based on electric energy. This self-regulating material may either be constituted by a ferromagnetic metal alloy which contactless is heated to the Curie-point in that a magnetic field affects the material. The Curie-point has been selected with a view of providing the desired therapeutic effect. An alternative heating element according to said prior art is one where the self-regulating material consists of a number of thin lamellae of so called PTC-elements having a selected Curie-point placed in a cylindric housing, heating taking place by means of an electric current under low voltage.

In the device according to said PCT-application the liquid medium is brought to circulate in the balloon so that effective heat transfer to the surrounding tissue is obtained, since otherwise the material´s self-regulating character would lead to a situation where the elements

would cut off and not give the necessary energy. Also in this case the circulation of the heat medium is obtained by the generation of a reciprocating movement which is then converted to circulation in the expanded balloon using a system of counter-positioned back valves. Also in this case the circulation contributes to a more even heat transfer to the surrounding tissues, which is essential for providing the desired effect.

It has, however, been found that devices working with forced circulation according to the two last-mentioned specifications are associated with serious disadvantages. These disadvantages are constituted by the formation of air pockets at certain positions in the system when the device is filled with the liquid which is intended to circulate in the system, and such air pockets in view of their high compressibility result in a strongly impaired circulation resulting in absence of the desired effect. This situation is explained by the fact that the air contained in a pocket is compressible so that the oscillating movement in the incompressible liquid is hampered. The sides where air pockets are formed during the introduction of liquid are for example in the device according to said US patent 4,160,455 in the bellow 29, at the manometer for pressure control 43 and also in the rubber bag 41. In the same manner air pockets are formed in the device according to said PCT-application at the piston syringe 25, the device 18 for pressure measurement and also in the balloon 25. It is true that it is conceivable to modify said devices by introducing special de-airiation valves at least at the pump devices and the pressure measuring devices, but such de-airiation valves result in a complication in design and operation and a cost increase in manufacture, the latter factor being a significant disadvantage, particularly in those cases when the catheters are of the disposable type.

Summary of the invention

The present invention has for its object to provide a new device for carrying out heat treatment, so called hyperthermia, while maintaining effective circulation of the heat medium.

Another object of the invention is to provide a device for carrying out hyperthermia, where the generation of air pockets in connection with filling of the device with a liquid heat medium is essentially prevented.

Yet an object of the invention is to provide a device for carrying out hyperthermia, in which the introduction of a liquid heat transferring medium takes place in one single operation in a simple manner.

A further object of the invention is to provide a device wherein the part which is contaminated in connection with its use is suited for mass fabrication at a reasonable cost and can therefore be disposed of after use.

For these and other objects which will be clear from the following description there is provided by the invention a device for carrying out heat treatment, so called hyperthermia, in a body cavity or duct, which device in a manner known per se comprises a catheter intended to be filled with a heat transferring medium and provided with an elongate front part intended to be introduced in said cavity or duct and comprising a centrally positioned heat-releasing element, which is either surrounded by an elongate housing or per se constitutes such housing, and a flexible and/or elastic balloon surrounding said housing in a liquid-tight manner. The device further comprises means for supplying energy to the element and an axially operating first inlet at the rear end of the housing for the supply of heat transferring medium to the housing and a housing outlet intended for the supply of said medium under pressure to the balloon for its expansion, and a second housing inlet positioned inside the balloon, and first means for expanding the balloon by the supply of heat transferring medium and second means for internal

circulation of said medium through the housing.

The device is characterized in that said second means is placed in series with said first means and said first housing inlet and comprises a first chamber of variable volume which via inlet and outlet form a connection between said first means and said first housing inlet, said first chamber and possibly other chambers with inlets and outlets in the catheter being arranged in such a manner that the highest point of each chamber is positioned at the same level or lower than the highest point of the transition of the chamber into the outlet, whereby avoidance of air or other gas being left when introducing heat-transferring medium is obtained.

It is preferred that said first chamber is arranged to have a periodically reduced and enlarged volume, said chamber in said connection being provided with a rear closable inlet and a front outlet which is in connection with said first housing inlet.

A preferred embodiment of the device according to the invention comprises for the formation of said first chamber as said second means a compressible and elastically reverting container which from the outside can be periodically compressed.

In order to provide the desired circulation of medium inside the balloon said housing outlet and said second housing outlet are each suitably provided with a back valve allowing flow of medium only in the intended direction. For this purpose the back valve in connection to the housing outlet thus allows flow only out from the housing, whereas the back valve in connection with the sacond housing inlet allows flow only into the housing.

Said second means for providing circulation of the medium through the housing suitably comprises a reciprocating element which via said container imparts a reciprocating movement to a determined quantity of medium.

As preferred embodiments for said first and said second means there may be used a conventional syringe and

an excenter device, respectively. The latter can comprise a conventional cam disc, an excenter or the like.

For the purpose of fascilitating removal of air or other gas that may remain in the system it is suitable to arrange at the front or distal end of the balloon a valve through which such remaining gas can be discharged or evacuated. This valve can suitably be of a so called fizzle valve but may alternatively be constitued by a valve provided with narrow passages or capillaries which allow the passage of gas but prevent the passage of liquid. In order that in possible evacuation of the balloon gas shall not flow back through said passages or capillaries a back valve can be arranged in said valve preventing such reentrance of gas. Such back valve can be constituted by a simple ball valve or a valve with a so called flap.

In a particularly preferred embodiment of the device according to the invention it is designed divided up into a catheter part comprising said elongate front part and said first chamber, and a central unit comprising the reciprocating element, said chamber may be part of a connecting house which releasably can be connected to the central unit for cooperation with said reciprocating element and which includes said rear closable inlet and said front outlet.

Said connecting house is preferably provided with a pressure release membrane accessible from the outside and suitably also a pressure sensing membrane also accessible from the outside. These both membranes can cooperate with a pressure sensor for sensing the pressure of the heat-transferring medium and with a backing controlling the release pressure for said heat-transferring medium. For the purpose of providing sufficient force onto the inside of the pressure release membrane exposed to the heat-transferring medium it is suitable that this exposure to the medium takes place in a chamber arranged in connection with the inside of the membrane, whereby the

medium under pressure affects said membrane via an enlarged exposed surface.

The device according to the present invention is suitably designed in such a manner that said connecting house is composed of two plates, wherein the passages or canals of said chambers are arranged inside one of the plates and/or in the other plate or in one or both of the opposed surfaces of the plates by corresponding recesses therein.

It is particularly preferred that said container and said membranes are arranged on the outside of one plate, suitably the bottom side of the lower plate, for cooperation with said reciprocating element, a pressure sensor and said backing controlling the release pressure of the medium.

It is suitable that said reciprocating element, the pressure sensor and the backing are arranged to be moved together to the desired cooperation with the connecting house when this is in position in the central unit. The connecting house is suitably provided with coupling means cooperating with corresponding means in the central unit, whereby electric energy can be supplied to the element for the heating of the heat-transferring medium.

In the device according to the invention said catheter part thus suitably forms a closed sterile system and is therefore suited for disposal, the central unit being used repeatedly and therefore not particularly cost-sensitive.

The heat releasing element can be of any type, especially based on heating by the supply of electric energy, but it is particularly preferred to use heat-releasing elements of the self-controlling type, for example of so called PTC-type. With regard to details concerning the type of elements, the arrangement for providing circulation of the heat-transferring medium and, optionally, other details reference is made to the above-mentioned PCT-application SE94/00208, the whole contents of which

are incorporated herein by reference.

In the present disclosure the expression "distal" and "proximal" are used with the meaning "front" and "rear", respectively, i.e. related to the operator of the instrument or the device.

Detailed description of the invention

The present invention will now be described further by exemplifying non-limiting embodiments in association with the appended drawings, wherein:

Figure 1 diagramatically shows an embodiment of the device according to the invention from which the principle design of the device can be seen;

Figure 2 shows a detail of the device in Figure 1;

Figure 3 shows a section along line I-I in Figure 2;

Figure 4 shows in section a detail of a valve device for the evacuation of gas from the system;

Figure 5 shows diagramatically a part of the device according to Figure 1, where the system for generating a reciprocating movement is shown;

Figure 6 shows diagramatically an assembly of a preferred embodiment of the device according to the invention;

Figure 7 shows a detail of the device in Figure 6;

Figure 8 shows a section taken along line IV-IV in Figure 7;

Figure 9 shows a section taken along line III-III in Figure 7;

Figure 10 shows a section taken along line I-I of a detail of the device in Figure 6;

Figure 11 shows an alternative embodiment of a detail of the device in Figure 6;

Figure 12 shows a sideview of the device in Figure 11;

Figure 13 and Figure 14 show a section taken along line I-I in Figure 11;

Figure 15 shows a section taken along line II-II in

Figure 11;

Figure 16 shows a section taken along line III-III in Figure 11;

Figures 17 and 18 show a cross-section through an alternative safety device for releasing pressure in the system; and

Figure 19 shows diagramatically in cross-section a preferred embodiment of the arrangement in connection to the container by which pulsation is generated.

Figure 1 shows diagramatically an embodiment of a balloon catheter according to the invention, said embodiment being shown in a very simplified form. The balloon catheter generally designated 1 comprises a distal part 3 provided with an expandable balloon 7 of for example highly elastic silicon, a central tube 9 having an axial proximal inlet 11, an inlet opening 12 and an outlet opening 13, the latter two openings enabling circulation of a liquid heat medium through central tube 9 and on its exterior inside the balloon wall. The distal part 3 further includes suitable heating means, such as a heat-releasing element 10 indicated in Fig. 1, and a number of counteracting backvalves, which are not shown in detail but are designed in accordance with the above-mentioned PCT-application SE94/00208 for providing circulation in the balloon when the medium enclosed in the catheter is subjected to oscillating pressure shocks.

The catheter tube 15 comprises inter alia ducts for the supply of liquid medium to the balloon 7 and conduits for the supply of electric energy to the element 10 and for the transfer of signals from sensors of pressure and temperature which may be positioned in association with the balloon 7. In the rear part of the catheter said electric conduits are separated in the form of a special cable 17, which via a coupling box 19 can be connected to a central unit to be described below. A liquid-tight elastic, compressible container 21 is connected to the

proximal end of the tube in series, and to the opposite end of this container 21 a closure valve 23 is connected and constitutes at the same time the proximal end of the catheter. In Fig. 1 there is also shown a filling means 25 for the supply of liquid medium in the form of a conventional syringe which is connected to valve 23, for example by a so called luer coupling.

In Fig. 2 the container 21 is shown seen from the side, and in Fig. 3 by a section taken along line I-I in Fig. 2. The container is in this embodiment constituted by two oppositely placed container halves 29,31, one bowl shaped, made of an elastic plastic film with good springing properties, for example polyethylene of high density. The container halves 29,31 are liquid-tight welded together along edges 33, whereas the open ends 35,37 are shaped as tubes.

The container 21 that may be massproduced at a very low cost is designed to form in cooperation with an exterior reciprocating member a pump device to impart an oscillating movement to the liquid medium contained in the catheter tube, said movement being transferred in the balloon 7 to circulation.

In view of the design of container 21 having an inlet part 35, an extended elasticly springing part 41 and an outlet part 37 and in view of the fact that the container is placed in series between filling means 25 and the catheter tube 15 introduction of heat transferring medium will be made possible without the formation of remaining air pockets in the pump device and the associated means.

The procedure for introduction of heat-transferring liquid medium to the device shown in Fig. 1 will be as follows. The sterile package of the catheter with the balloon 7 in an unexpanded state are removed from the package, the syringe 25 is completely filled with the

liquid to be used as a heat-transferring pressure medium and is then connected to the valve 23 via the coupling 27. The catheter filled with air is suitably held in a vertical position with the distal part pointing upwardly, as shown in Fig. 1. When the piston of syringe 25 is moved forward the liquid will move forward and upward at the same time as the air contained in the catheter starts to fill up the balloon without air being remaining in the container 21. The filling is concluded when the liquid level has reached a certain position 10 in the balloon 7, as shown in Fig. 1. Above this level the air previously contained in the catheter will be collected under a certain pressure around the outlet opening 13.

The air contained in the ballon 9 can now be removed in two different ways. One way is to place the catheter with syringe 25 vertically but with the balloon 7 pointing downwardly. The contained air will thereby assemble around inlet opening 12. Liquid medium is then sucked back upwardly and into syringe 25, the air in the balloon 7 being entrained and followed by the liquid present in the proximal part of the balloon at the same time as the expanded balloon reduces in volume. When part of the liquid medium and all air has been collected in this manner in syringe 25 only a liquid medium remains in the catheter. The valve 33 is then closed, and the syringe is removed and air is ejected out of the syringe which is now again filled with liquid and then connected to the catheter now free of air.

Another possibility is to remove the air which after the filling procedure according to the above has collected in the upper distal part of the balloon consists in removing the air through a valve arranged in the distal end of the balloon 7. Such device is illustrated in Fig. 4, where the distal part 45 of central tube 9 is provided with outlet openings 47 corresponding to the opening 13

as shown in Fig. 1. One backvalve 49 for the circulation is in this embodiment constituted by a ball 51 and an associated valve seat 53. In the distal end of central tube 9 a second valve 55 is arranged which has the form of a ball 57 engaging a corresponding seat 59 by means of a spring 61. In the seat of valve 55 an outlet opening 63 is arranged. In Fig. 4 the distal part 64 of balloon 7 is shown.

When all air has been collected under pressure at the distal part 64 of the balloon in the manner described above valve 55 is opened by a fine needle being inserted through opening 63 so that complete de-airiation of balloon 7 can take place in view of the pressure from the expanded balloon.

An alternative valve device allowing de-airiation of balloon 7 can be constituted by a fibre plug of for example teflon provided with fine canals or capillaries which have the ability of only letting through gas but not allowing passage of liquid. As previously mentioned such fibre plug may suitably be combined with a back valve or one-way valve of a simple type preventing re-entrance of gas in case that the balloon has to be evacuated. An example of suitable material for use in such fibre plug is polyethylene of high density (HDPE), for example a material from POREX Technologies, Georgia, USA, having an average pore size of 60 µm and a pore volume range of 45-55%.

After the catheter has been filled with liquid medium in the manner described above it can be connected to a central unit which can comprise inter alia means for control and stearage of the course of treatment with regard to temperature, pressure and time, and an energy source in the form of for example a low-voltage direct current battery, and means to impart an oscillating movement to container 21.

In Fig. 5 there is illustrated diagramatically in a simplified form a device to provide circulation of the liquid medium within balloon 7. The device to impart an oscillating movement to container 21 comprises a fixed jaw 65 and a juxtaposed movable jaw 67 which is imparted a reciprocating movement upwardly and downwardly by a rotary excenter disc 69 which can be driven by a motor not shown. Container 21 is held by engagement between jaws 65,67. The cable 17 of the catheter is via the coupling box 19 connected to a central unit 71 indicated by dashed lines in Fig. 5.

The hyperthermia treatment is started by insertion of the unexpanded balloon filled with liquid into the cavity of interest, for example uterus, whereafter the balloon is expanded to a suitable pressure by pressure actuation from syringe 25 after closure of valve 23. After the valve 23 has again been closed the treatment proper is started by means of actuation from central unit 71 in that the pump unit 67,69 is started so that the medium is brought to circulate in the balloon 7, heating is initiated by supply of current via cable 17 to the heat element 10 in the central tube 9 until the correct temperature has been reached. Control of temperature and control of pressure can take place in a manner known per se by cooperation between sensors in the distal part of the catheter and the central unit via cable 17.

Another preferred embodiment is shown diagramatically and in perspective in Fig. 6. According to this embodiment the catheter is constituted by one single unit comprising the catheter tube 15 with balloon 7 connected at the distal end thereof and at the proximal end thereof a connecting housing 75 containing an elasticly resilient container corresponding to container 21 in Fig. 1 for pumping of the liquid medium, further connecting means and ducts for the supply of liquid medium and a coupling

box 77. The central unit 71 is in this embodiment constituted by a box 79 having a front 81 including manoeuver and control means, display 83 etc. In central unit 71 there is also a socket recess 85 for insertion of the connecting housing 75. In the bottom 87 of recess 85 there is an opening 88, wherein a moveable jaw 67 affected by an excenter disc corresponding to disc 69 in Fig. 5 is active for imparting an oscillating pumping movement to the container arranged in the connecting housing 75. In recess 85 there is also a coupling member 89 cooperating with the coupling box 77 of the connecting housing.

The flat proximally arranged connecting housing 75 is shown in detail in Figs. 7-10. In Fig. 10 the connecting housing 75 is shown in a longitudinal section taken along line I-I in Fig. 6. The connecting housing 75 is designed with two plates joined together, one upper half 90 and one lower half 91, the latter being shown seen from the above in Fig. 7. On the lower side of the lower plate 91 an elasticly resilient container 93 corresponding to container 21 in Fig. 5 is arranged. However, in this case container 93 is bowl-shaped and liquid-tight connected to the lower side of the lower plate 91. In plate halves 89 and 91 which suitably can be massproduced by for example extrusion, there is a space 95 for insertion and attachment of the catheter tube 15 and another narrower space 97 in the rearward extension of space 95 for the attachment of a liquid tube passing through the catheter. For the electric conduits required and described in connection with Fig. 1 a special duct 99 is arranged which is formed by two juxtaposed recesses in the upper and the lower plate 89,91. These open into a space 101 intended to accommodate a coupling box. In the upper plate 89 there is a connecting means 103 which allows the attachment of a suitable liquid introduction means, such as a syringe. In the upper and the lower plate 89 and 91,

respectively, also connecting ducts 105,107 extending in the plane of the plate halves, and in the lower plate 91 two verticle through-ducts 109, 111 are arranged, which are juxtaposed and open adjacent to the inner edge of the bowl-shaped container 93. In this manner a duct connection is established between connecting means 103 and space 97 via ducts 107 and 111, container 93 and ducts 109 and 105.

When assembling the device according to Fig. 6 the liquid-conducting catheter tube extending in the proximal end of catheter tube 15 is separated from the exterior system of electric conduits 17. The end of catheter tube 15 is then inserted into and fixed in space 95 (Fig. 10) at the same time as the end of the liquid-conducting catheter tube is placed in space 97 and the electric conduits in duct 99. The latter are connected to a suitable contact device 77 (Fig. 6) present in space 101 (Fig. 7). The two plate halves 89,91 are then attached to each other in a liquid-tight way.

When using the assembled catheter connecting housing 75 is inserted in space 85 in the central unit 71, whereby contact is obtained between the contact means 77 and a corresponding contact means 89 in the central unit 71 (Fig. 6). A syringe or other suitable filling means filled with liquid is then connected to the connecting means 103, whereafter introduction of liquid can take place from the syringe. In connection herewith the air enclosed in the duct system and the catheter tube is moved forward and into balloon 7 which partly expands. When the liquid column enters the bowl-shaped container 93 it will first cover the bottom of the bowl and then extend upwardly at the same time as a corresponding volume of air is displaced through ducts 109 and 105 into the liquid-conducting tube of the catheter. In this manner all air in the system is transferred to the end of balloon 7 and can be re-

moved according to either of the two methods previously described in connection with Fig. 1.

When the connecting housing 75 has been positioned in central unit 71 opening 88 will come to a position opposite to container 93. By a suitable device not shown here an element is now lifted to engagement against the container 93 from below and imparts a pulsating movement to container 93. This can be provided for example by rotary excenter disc according to the principle shown in Fig. 5.

The catheter is now ready for hyperthermal treatment and its distal part can in an unexpanded state be inserted into the cavity to be treated. The expansion of balloon 7 takes place by introduction of liquid to a suitable pressure which can be read on the central unit 71 by signals from a pressure sensor arranged in connection to the distal part of the catheter, said sensor being connected to the coupling box of the central unit via an electric conduit. The treatment is then started by imparting an oscillating movement, for example by an excenter disc, to container 93 so that the liquid is brought to circulate in the balloon while applying electric energy to heat element 10 in the balloon so that the circulating liquid is heated to the desired temperature.

In Figs. 11 to 16 there is shown an alternative embodiment of the invention comprising a catheter having a connecting housing 75' containing not only the connecting means for liquid, means for providing an oscillating movement of the liquid and means for connecting electric conduits to the central units but also a safety device for rapid pressure release and means for measuring the pressure in the system. All these means are coupled in series and connected by a system of ducts, whereby heat-transferring liquid medium can be introduced into the

system in one operation so that the air of the system is transferred up to the balloon substantially avoiding air pockets. The air can thereafter be removed in the same manner as described in connection to Figs. 1, 4 and 10.

The embodiment of the invention shown in Figs. 11 to 16 comprises in the same manner as earlier a connecting housing 75' shown in Fig. 11 from above. In Fig. 12 the connecting housing 75' is shown seen from its distal part in a horisontal position. From Fig. 12 it is clear that housing 75' consists of two plate halves 115,117, the lower plate half 117 carrying at its lower side a bowl-shaped elasticly resilient container 119. In Fig. 11 circular recesses 121,123,125 are shown by point-dashed lines in the lower side of the lower plate half 117, said recesses being intended for the attachment of two membranes 127,129 as shown also in Figs. 13 -16 and the container 119.

In Fig. 12 there is shown the bowl-shaped container 119 corresponding to container 93 in Fig. 10 and intended to impart a pulsating movement to the liquid pressure medium when the catheter is filled with liquid. Container 119 as well as membranes 127,129 are tightly connected to the lower plate half 117 by means of its flange 120 pressed into the circular recess 125. From Fig. 12 it is also clear that the opposite plate halves 115,117 are provided with recesses forming round openings, of which opening 121 is an inlet opening for introduction of liquid into the catheter via the dashed ducts 131,133,135,137,139, in Fig. 11, said ducts in turn establishing connection between membranes 127,129 and container 119.

In a corresponding manner opening 141 forms an attachment opening for connection to the catheter tube 15. A third opening 143 alternatively constitutes an outlet opening for a duct 144 arranged in connection to membrane 127 and serving as an alternative safety device for re-

leasing possible non-desired overpressures in the system, which will be explained in the following.

In Fig. 13 there is shown in a section taken along line I-I in Fig. 11 an embodiment of a safety device intended for releasing a too high pressure in the system. In the joint plate halves 115,117 there are two juxtaposed recesses forming duct 141 and duct 143, the latter serving as a duct for electric conduits for the supply of energy from a contact means 145 arranged in the distal end of connecting housing 75' in accordance with Fig. 11. Fig. 13 furthermore shows two ducts 147,149 which for practical reasons have been formed only in the upper plate half 115 and which constitute part of the earlier connecting ducts between the inlet opening 121 and the membranes 127,129.

Ducts 147,149 are mutually connected by means of two vertical ducts 151,153 arranged in the lower plate half 117 via the horisontal duct 133. Previously mentioned membrane 127 engages sealingly against the lower side of the lower plate half 117 under the action of a piston 155 which is actuated by a spring 157 the spring power of which has been selected so that full sealing will be obtained when normal overpressures are present in the system. If, however, for some reason the pressure in the system increases above a certain allowed maximum value the pressure of the liquid in ducts 151,153,133 exceeds the spring force acting on piston 155. In Fig. 14 there is shown the condition thereby appearing when the membrane 127 and therefore piston 155 are pressed downwardly under the formation of a space 159 filled with liquid, whereby in this manner the pressure in the system is rapidly released. If then the pressure reverts to normal piston 155 and thereby membrane 127 are moved to a sealing position against the lower side of the lower plate

half 117. In this embodiment the overpressure is thus released in view of the fact that membrane 127 is pressed downward to form a space 159 which can be filled with liquid.

Fig. 15 shows another embodiment of safety device in the form of a detail-section along line III-III in Fig. 11. In this embodiment membrane 127 is sealingly pressed against the same duct system 147,149,133 by piston 155 corresponding to the device in Fig. 13. According to Fig. 15 the opening of a vertical duct 150 is opened when the membrane 127 is pressed upwardly by overpressure, said duct 150 being connected with outlet opening 143 via duct 144 at the upper end thereof.

As previously mentioned connecting housing 75 may suitably also comprise a device for measuring the pressure in the system. A preferred embodiment to provide this function is shown in Fig. 16 illustrating a detail in a section taken along line II-II in Fig. 11. In the lower plate half 117 membrane 129 is sealingly arranged on the lower side and is via a capillary 165 connected to a duct 137 arranged in the upper plate half 115. This duct 137 constitutes part of the duct system in series connecting the different membranes as previously described. In connection with membrane 129 a load cell 167 of a known type is arranged which can release impulses to a control means for measuring pressure in dependence of the pressure prevailing in the system.

In Figures 17 and 18 there is shown another embodiment of a safety device intended to release pressure in the system if it becomes too high. This safety device generally designated 201 is shown as previously in connection to Figures 13-15 in a detail-section through the two plate halves 115',117'. The lower plate 117' is on the lower side thereof provided with a ring-shaped recess 207

corresponding to duct 133 in Fig. 13. In the middle of this recess 207 there is found in connection to a central part or a central hub 208 a vertical central duct 215 opening into a discharge duct 209 corresponding to duct 143 in Fig. 11. In connection with the annular recess 207 vertical ducts 211,213 are arranged corresponding to ducts 151,153 in Fig. 13.

As previously the safety device is provided with a membrane 127 which can engage against the lower plate 117' by means of a piston 203 pressed to sealing engagement against the membrane by a spring 205. This piston 203 is, in connection with a central recess 223 provided with a central backing 221 by which membrane 127 can be brought to particular engagement against hub 208 thereby providing sealing of the central duct 215 by means of the membrane 127. Backing 221 is made of an elastic, i.e. resilient material, for a purpose to be described further below.

The safety device shown in Figures 17 and 18 operates briefly in the following manner.

In connection with imparting an oscillating movement to container 19 by for example an excenter disc, the heat-releasing medium is brought to circulate in the balloon under heat transfer to the surrounding walls of the cavity or duct. The pressure hereby arising varies according to a sinus function with maxima and minima a certain average pressure arising in the system. This average pressure is so adapted that it is suitable for the treatment in question and piston 203 with spring 205 is brought to engagement against membrane 127 and the lower side of plate 117' with a pressure somewhat exceeding the average pressure of the system.

If, however, the pressure in the system varies according to a sinus function the maximum pressure will ex-

ceed the opening pressure for the safety device, membrane 127 with piston 203 being pressed downwardly to the position shown in Fig. 18. This would normally result in liquid leaking out via the annular recess 207 and the central conduit 215 to the discharge duct 209 which would result in continuous discharge of heat-transferring medium from the system. However, such discharge is prevented by the central backing 221 contained in piston 203 through the elasticity of which the central duct 215 is maintained closed so that leakage of medium is prevented. If, however, the pressure will be too high for a longer period of time also this duct 215 will be opened so that the pressure in the system will be released and damaging effect of a too high pressure will be avoided.

In Fig. 19 there is shown a detail of the arrangement in connection to the container 119 which is arranged on the lower side of plate 117 and which in cooperation with an excenter device, for example according to Fig. 5, provides the pulsation used for circulation of the medium within balloon 7. In relation to the embodiment shown in Fig. 11 the embodiment according to Fig. 19 contains in the chamber formed by container 119 and the lower surface of plate 117 a dome-shaped recess 251, the uppermost part of which via a vertical duct 253 is in connection with duct 139 as shown in Fig. 11. The inlet duct 142 also shown in Fig. 11 is via a vertical duct 255 connected to the chamber formed by container 119.

When filling the catheter with heat-transferring medium via inlet opening 141 and duct 142 (Fig. 11) container 119 via the vertical duct 255 is supplied with medium, the container 119 being filled from below so that the air is collected at the highest part of dome 251 and leaves via passage 253 and duct 139 for transfer to the space inside the pressure sensing membrane 129. In this manner the formation of non-desired air pockets in the sys-

tem in connection to container 119 is thus avoided.

It can be added that when connecting housing 75' has been positioned in central unit 71 the excenter jaw 67 (Fig. 5), the backing against the pressure releasing membrane 127 and the load cell 167 can be arranged on a common platform which by some device not shown will be lifted up against connecting housing 75' for cooperation with container and membrane.

As is clear from the above description of preferred embodiments the present invention provides a balloon catheter device by which heat treatment, so called hyperthermia, can be carried out in a simple and efficient manner. This device enables safe and simple operation while avoiding the presence of air pockets, as in the prior art devices. In this manner effective circulation of the heat-transferring medium in connection to the heat element inside of the catheter balloon will be obtained, so that heat treatment can be carried out under reproducible conditions with regard to temperature and pressure and with even heat transferred to the surrounding walls of the cavity will be obtained.

The catheter device according to the invention may be designed in a practically useful way with a distal catheter part manufactured at a low cost and thus disposable and a central unit that can be used for a long time and is therefore not cost sensitive. This system means at the same time that the sterility problem can be solved in a simple manner since the central unit cannot be contaminated during the heat treatment involved.

It should be observed that the invention is not restricted to the embodiments described which can be modified in many ways within the frame of the scope of the appended claims. Such changes and modifications which are clear to the skilled artisan can be made within the frame

of the inventive concept as reflected by the design of the appended claims.

CLAIMS

1. Device for carrying out heat treatment, so called hyperthermia, in a body cavity or a duct, comprising a catheter intended to be filled with heat-transferring medium and provided with an elongate front part (3) intended to be introduced into said cavity or duct and comprising a centrally positioned heat-releasing element (10), which is either surrounded by an elongate housing (9) or per se constitutes such housing, and a flexible and/or elastic balloon (7) surrounding said housing (9) in a liquid-tight manner, further comprising means (17;19) for supplying energy to the element and an axially operating first inlet (11) at the rear end of the housing for the supply of heat-transferring medium to the housing (9), and a housing outlet (13) intended for the supply of said medium under pressure to the balloon (7) for its expansion, and a second housing inlet (12) positioned inside the balloon, and first means (25) for expanding the balloon by the supply of heat-transferring medium, and second means (21;93) for internal circulation of said medium through the housing (9), characterized in that said second means (21;93) is placed in series with said first means (25) and said first housing inlet (11) and comprises a first chamber (29) of variable volume which via inlet (35) and outlet (37) forms a connection between said first means (25) and said first housing inlet, said first chamber and possibly other chambers with inlets and outlets in the catheter being arranged in such a manner that the highest point of each chamber is positioned at the same level or lower than the highest point of the transition of the chamber (29) into the outlet (37), whereby avoidance of air and other gas being left when introducing heat-transferring medium is obtained.

2. Device according to claim 1, characterized in

that said first chamber is arranged to have a periodically reduced and enlarged volume, said chamber in said connection being provided with a rear closable inlet (35;121) and a front outlet (37;141) which is in connection with said first housing inlet (11).

3. Device according to claim 2, characterized in that for the formation of said first chamber said second means comprises a compressible and elasticly reverting container (21;93) which from the outside can be periodically compressed.

4. Device according to claim 1, 2 or 3, characterized in that said housing outlet (13) and said second housing inlet (12) are each provided with a backvalve allowing flow of medium in only the intended direction.

5. Device according to anyone of the preceding claims, characterized in that said second means comprises a reciprocating element (67;69) imparting to a determined quantity of medium a reciprocating movement.

6. Device according to claim 5, characterized in that said second means comprises an excenter (69).

7. Device according to anyone of the preceding claims, characterized by a valve (55) arranged at the distal end of housing (9) by which air remaining in the system can be evacuated, said housing (9) at its distal end extending at least up to the front wall of balloon (7) to which it is fixed.

8. Device according to claim 7, characterized in that said valve (55) is a so called fizzle valve which can be actuated from the outside.

9. Device according to claim 7, characterized in that said valve (55) is provided with narrow passages or capillaries allowing passage of gas but not of liquid.

10. Device according to any one of claims 4 to 9, characterized in that it is divided up into a catheter part (1) comprising said elongate front part (3) and said

first chamber, and a central unit (71) comprising said reciprocating element (67), said chamber being part of a connecting house (75;75´) which can be releasably connected to the central unit (71) for cooperation with said reciprocating element (67) and which includes said rear closable inlet (121) and said front outlet (141).

11. Device according to claim, characterized in that said connecting house (75´) comprises a pressure release membrane (127) exposed to the medium in said second chamber.

12. Device according to claim 9 or 11, characterized in that said connecting house (75´) comprises a pressure release membrane (129) accessible from the outside.

13. Device according to claim 12, characterized in that said membrane (127;129) is placed in series in a canal between said first means (25) for the expansion of the balloon and the inlet of said first chamber (29;119).

14. Device according to any one of claims 10 to 13, characterized in that said connecting house (75;75´) is composed of two plates (115,117) wherein the passages or canals of the chambers are arranged in one plate and/or in the other plate or in the juxtaposed surfaces of one or both of the plates (115,117).

15. Device according to claim 14, characterized in that said container (29;119) and said membrane (127,129) are arranged on the outside of one plate (117) for cooperation with said reciprocating element (67;69), and a pressure sensor (167) and a backing (155) regulating the release pressure of the medium.

16. Device according to claim 15, characterized in that said element (67), pressure sensors (167) and backing (155) are arranged to be moved together to the desired cooperation with connecting house (75;75´) when positioned in the central unit (71).

17. Device according to any one of claims 10 to 16,

charcterized in that the connecting house (75;75′) is provided with coupling means (77) cooperating with corresponding means (89) in the central unit (71), whereby electric power can be supplied to the element (10).

18. Device according to any one of the preceding claims, characterized in that said heat-releasing element (10) is of the self-regulating type.

19. Device according to claim 18, characterized in that said heat-releasing element (10) is of so called PTC type.

20. Device according to any one of claims 10 to 19, characterized in that said catheter part (1) forms a closed sterile system and is of a disposable type.

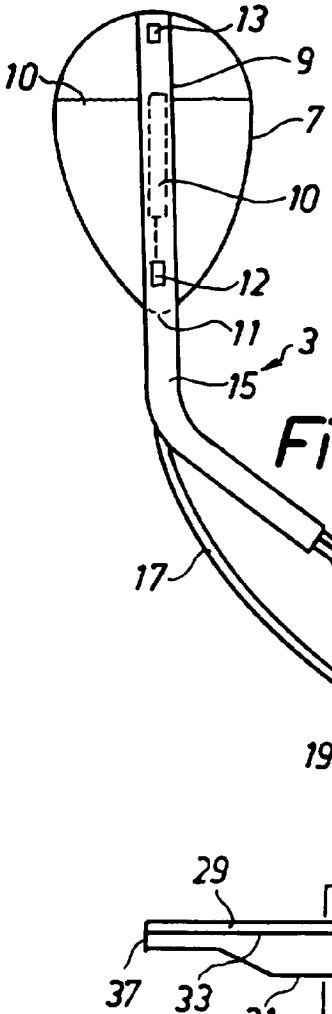

Fig. 1

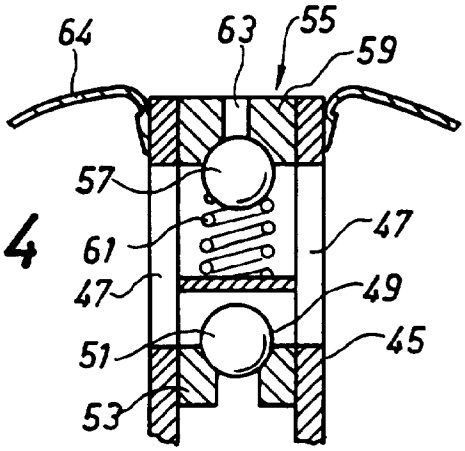

Fig. 4

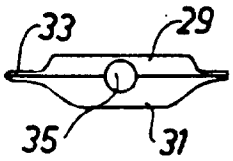

Fig. 3

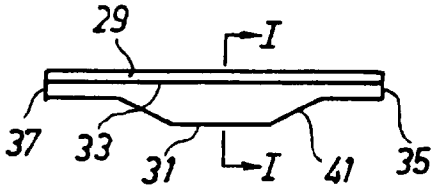

Fig. 2

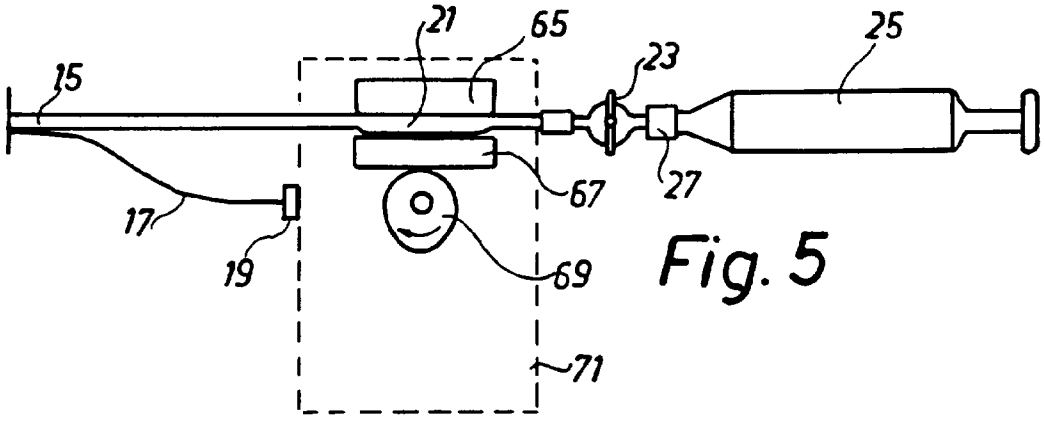

Fig. 5

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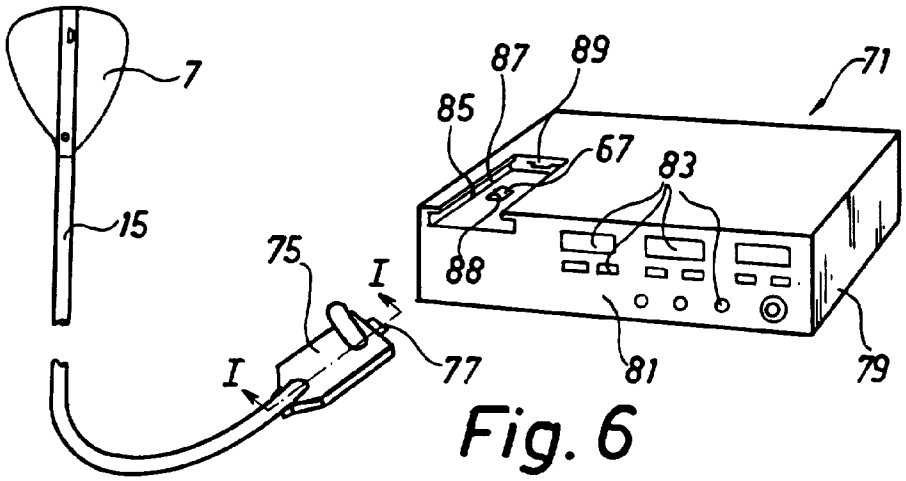

Fig. 6

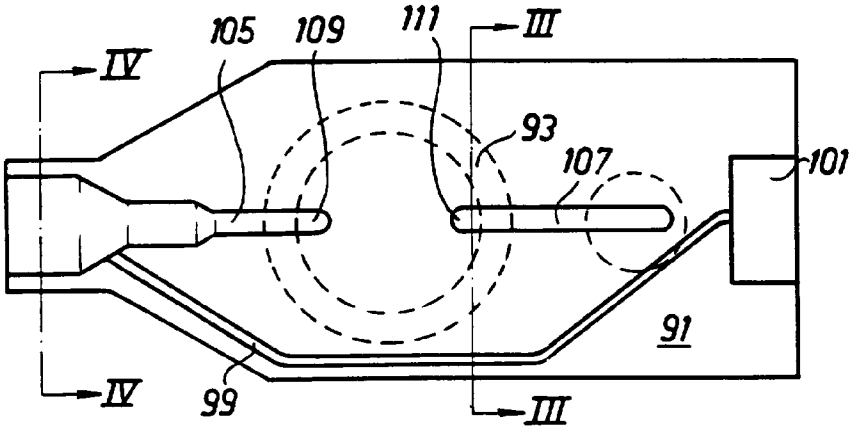

Fig. 7

Fig. 9

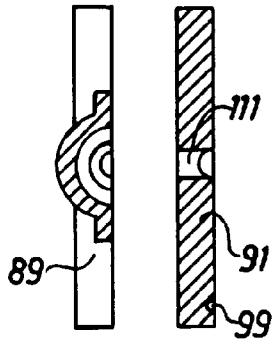

Fig. 8

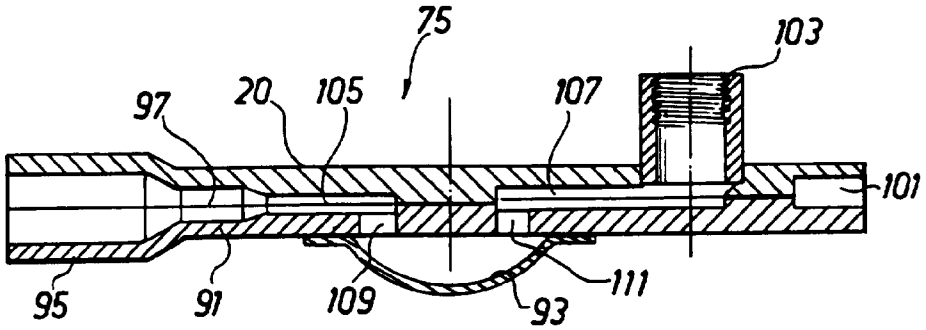

Fig. 10

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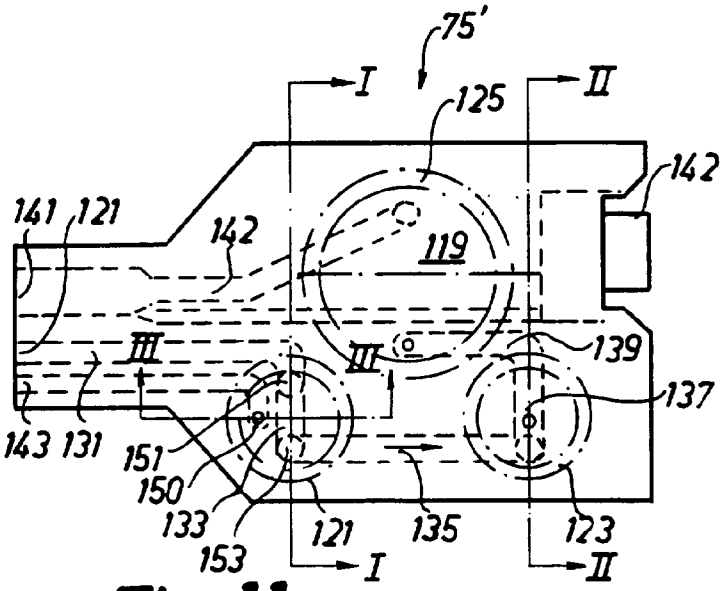

Fig. 11

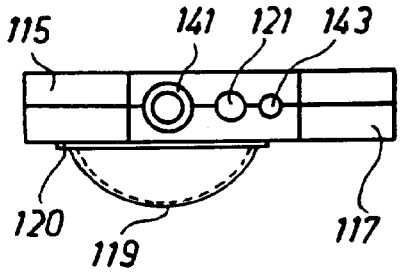

Fig. 12

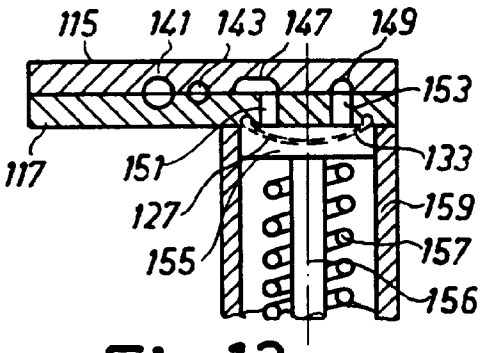

Fig. 13

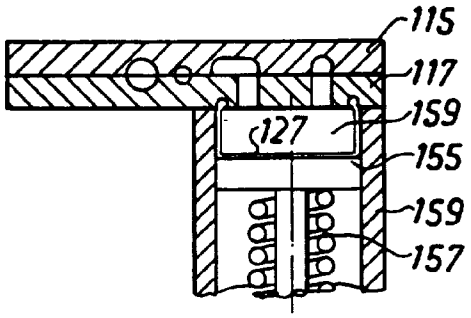

Fig. 14

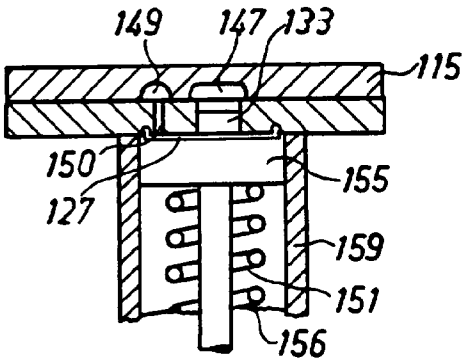

Fig. 15

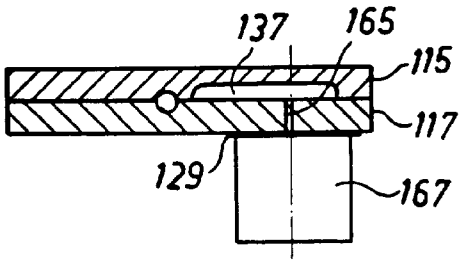

Fig. 16

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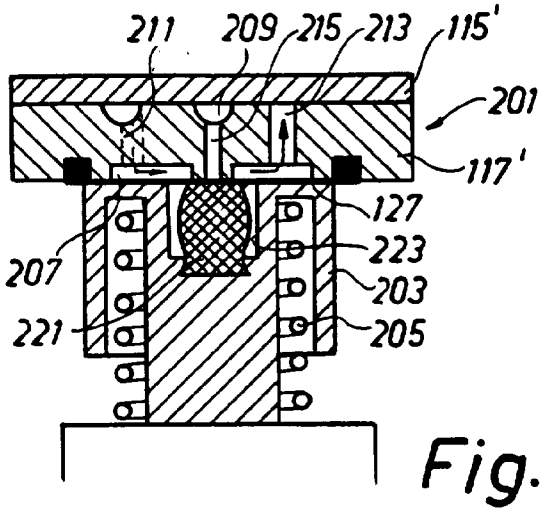

Fig. 17

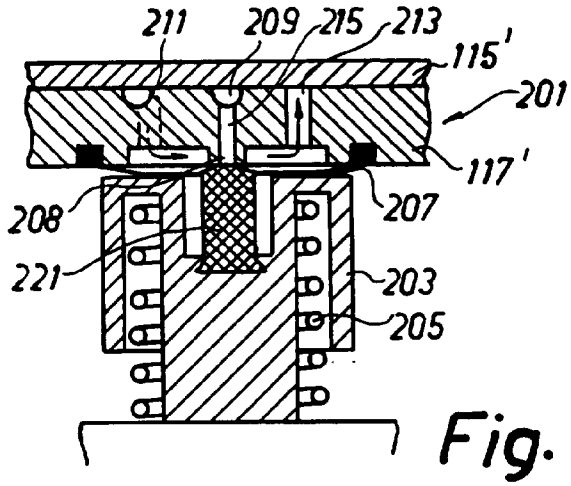

Fig. 18

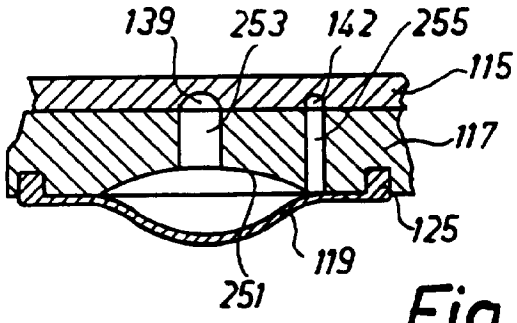

Fig. 19

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 95/01376

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 7/12 // A 61 M 29/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F, A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

QUESTEL 2

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 9421203 A1 (PACKARD DEVELOPMENT S.A.), 29 Sept 1994 (29.09.94), page 7, line 6 - page 9, line 8, figures 1-3,13	1-6,10,17-20
A	US 4160455 A (JAMES T. LAW), 10 July 1979 (10.07.79), column 2, line 30 - line 55, figure 1	1-3,5-6

☐ Further documents are listed in the continuation of Box C. ☒ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" erlier document but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed
"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25 March 1996	26.03.1996
Name and mailing address of the ISA/ Swedish Patent Office Box 5055, S-102 42 STOCKHOLM Facsimile No. +46 8 666 02 86	Authorized officer Leif Brander Telephone No. +46 8 782 25 00

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

05/02/96

International application No.
PCT/SE 95/01376

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO-A1- 9421203	29/09/94	NONE	
US-A- 4160455	10/07/79	DE-A- 2731276	19/01/78
		GB-A- 1582135	31/12/80

Form PCT/ISA/210 (patent family annex) (July 1992)